

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Serial No. : 09/763,267 Confirmation No.: 5473

SUPPLEMENTAL AMENDMENT - Remarks

In the Office Action mailed February 13, 2003, the Examiner has rejected claims 7-10 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the temperatures in the claims. Applicant herein amends claims 7-10 to correspond to the temperatures found in the specification, and respectfully requests that this rejection be withdrawn.

The Examiner has rejected claims 6-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner finds the phrase "slightly above the melting point" in claim 6 to be indefinite. Applicant herein amends claim 6 to remove the word "slightly" and respectfully requests that this rejection be withdrawn. In claims 7 and 9, the Examiner states that the limitation "first heated sealing surface" lacks antecedent basis, as does the phrase "second heated sealing surface" in claims 8 and 10. Applicant herein amends claims 7 - 10 to replace "heated sealing surface" with "heated sealing head" and respectfully requests that this rejection be withdrawn. Also in claim 10, the Examiner finds the intent of the phrase "second heated sealing surface has a temperature of about 200°C" to be unclear because this temperature is the same as that of the first heated sealing surface,

yet the surfaces are required to have different temperatures. Applicant amends claim 10 to require a temperature of 80°C; the earlier temperature was a clerical error. Support for the amended temperature can be found in the specification on page 8.

The Examiner has rejected claims 1, 4, 6 and 8-12 under 35 U.S.C. 103(a) as being unpatentable over the admitted prior art disclosed in the specification in view of Doering, Jr., U.S. Patent No. 3,813,846 ('846). The Examiner states that the prior art discloses a method for producing hot sealed packs for TTS but does not disclose the heated sealing heads including two or more contact areas and advancing the pack material from the first contact area to the second contact area for additional heat sealing. However, the Examiner states that heated sealing heads with two or more contact areas and advancing the pack material into additional contact areas for additional sealing are well known and conventional; the Examiner uses '846 (col. 4, lines 20-43) to illustrate this. The Examiner concludes that it would have been obvious to one skilled in the art at the time of the invention to provide a heated sealing mechanism with multiple contact areas and moving the material through sequential sealing operation with heat and pressure as disclosed by Doering Jr. in the method of the admitted prior art to provide a good seal with high throughput.

Applicant respectfully traverses this rejection. Applicant amends claims 1 and 4 herein to more clearly define the invention. Specifically, applicant amends these claims to claim identical contact area structures; support for this amendment can be found in the specification on page 4, last paragraph. Applicant respectfully states that the gist of the present invention is the combination of a reduced sealing temperature with the use of repetitive sealing steps to produce hot-seal packs for transdermal therapeutic systems without

reducing the cycle rate of the welding machine. Reduction of the sealing temperature such that the pack material won't be damaged and provision of intact welding seams is achieved by using a sealing tool comprising two cooperating heated sealing heads having different temperatures, the first sealing head having a temperature above the melting point of the polymer and the other heated sealing head having a temperature below the melting point of the polymer, and adjusting the temperature of the heated sealing head having a temperature above the melting point of the polymer from a temperature considerably higher than said melting point to a temperature only slightly above said melting temperature, and of adjusting the temperature of the second sealing head to a temperature considerably below said melting point. This means that, in the case of HDPE, the temperatures of the sealing heads are reduced from 197°C and 72°C to 169°C and 65°C for the first and second sealing head respectively. In the case of BAREX, the temperature of the second sealing head could be reduced from 200°C to 80°C.

The affects of temperature reduction are compensated for by using repetitive sealing steps utilizing a sealing tool comprising two cooperating sealing heads having in succession in the direction of advance, two or more contact area structures corresponding to the predetermined weld lines, wherein the two heated sealing heads of the sealing tool have the same contact area structure, see the specification on page 4, last paragraph. In contradistinction, '846 discloses a grid of engageable bars in the longitudinal direction (69, in Figures 4, 5, and 7) and traverse bars (68) which are not heatable. Only the upper die member (64) of '846 is heated (column 3, last paragraph).

Although it may be known from admitted prior art that HDPE may be welded if two

cooperating sealing heads having a temperature of 197°C, which corresponds to about 200°C, and 72°C respectively, are used, the skilled artisan can not infer from admitted prior art and '846 that proper welding seams may successfully be achieved if the temperature of at least one sealing head will be reduced such that one sealing head has a temperature slightly above and the other sealing head considerably below the melting point of the weldable polymer, in particular if said polymer is a polyacrylonitrile.

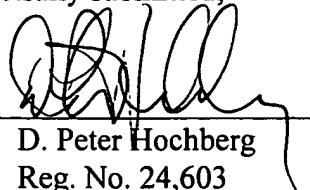
Applicant believes that the combined view of admitted prior art and '846 would not lead the skilled artisan to reduce the temperatures of the sealing heads as taught by the present invention with the expectation of successfully achieving intact welding seams. If at all, the skilled artisan would contemplate a welding apparatus according to '846 comprising lower heated longitudinal and transverse bars being heated to the temperatures according to admitted prior art to further facilitate the complete sealing.

It should further be acknowledged that '846 teaches a method and an apparatus for sealing covers to trays. This is a very specific application of heat sealing, and '846 neither addresses nor even mentions the problem of incomplete welding seams or excessive pinching of the melted polymer upon heat sealing, which are the problems leading to the present invention. Therefore, '846 does not provide any motivation for the skilled artisan to amend the sealing conditions or to contemplate the present invention. Accordingly, applicant respectfully requests the withdrawal of this rejection.

It is respectfully submitted that the application is now in condition for allowance, and such action is requested. No new matter has been added. The examiner is invited to telephone the undersigned if there are any matters which could be discussed to expedite the

prosecution of the above-identified application.

Respectfully submitted,

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